### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

MDL NO. 1456

Master File No. 01-CV-12257-PBS

THIS DOCUMENT RELATES TO: (State of Nevada v. American Home Products

Corp., et al.,

02-CV-12084-PBS)

Judge Patti B. Saris

# ANSWER AND DEFENSES OF DEFENDANT ASTRAZENECA PHARMACEUTICALS LP AND ZENECA INC. TO THE STATE OF NEVADA'S AMENDED COMPLAINT

Defendants AstraZeneca Pharmaceuticals LP ("AZPLP") and Zeneca Inc.<sup>1</sup> (collectively "AstraZeneca"), through its undersigned counsel, answer the State of Nevada's Amended Complaint served via Verilaw on August 1, 2003, in the above-captioned action as follows:

#### I. INTRODUCTION

1. Admits that Plaintiff purports to bring this case as alleged in paragraph 1, but denies the allegations in paragraph 1, specifically denies the existence of or participation in an "Average Wholesale Price Inflation Scheme," denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca, and otherwise denies knowledge or

<sup>&</sup>lt;sup>1</sup> The entity listed as AstraZeneca US does not exist. Although AstraZeneca PLC is referenced in the Amended Complaint, it is not named as a defendant.

information sufficient to form a belief as to the truth of the allegations in paragraph 1 as to the other parties.

- 2. Admits that AZPLP manufactures, sells, and/or distributes pharmaceutical products in the United States. To the extent the allegations in paragraph 2 refer to statutory or regulatory programs, the statutes, regulations, and other sources regarding those programs speak for themselves, and any characterizations thereof are denied. AstraZeneca denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 as to the other parties.
- 3. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, except admits that the development of new drugs can benefit individuals.
- 4. Denies the allegations in paragraph 4 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 as to the other parties.
- 5. Denies the allegations in paragraph 5, except admits that some private and public drug reimbursement systems reimburse physicians and pharmacies based upon the AWP for some prescription drugs, as published and reported by various independent third-party publications, but denies the remaining allegations in paragraph 5 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 as to the other parties.

- 6-7. Denies the allegations in paragraphs 6-7 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme," as alleged in paragraphs 6-7, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 6-7 as to the other parties and entities.
- 8-10. Denies the allegations in paragraphs 8-10 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 8-10 as to the other parties.
- 11-12. Plaintiff's "Best Price" claims against AstraZeneca have been dismissed by Court Order dated June 10, 2004 for all AstraZeneca drugs except Zoladex. To the extent that an answer is required, AstraZeneca refers to the statutes and regulations referenced in paragraphs 11-12 for their content, which speak for themselves, and otherwise denies the allegations in paragraphs 11-12 directed at AstraZeneca.
- 13. Denies the allegations in paragraph 13 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 as to the other parties.
- 14-17. Denies the allegations in paragraphs 14-17 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme" or "Best Price Scheme," as alleged in paragraphs 14-17, and otherwise denies knowledge or information sufficient to

form a belief as to the truth of the allegations in paragraphs 14-17 as to the other parties.

- 18. Admits that Plaintiff seeks to recover costs as actual damages and/or restitution, but denies the allegations of paragraph 18, and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca.
- 19-20. Denies the allegations in paragraphs 19-20 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme," as alleged in paragraph 19, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 19-20 as to the other parties.
- 21. Admits that Plaintiff seeks restitution through its *parens* patriae and statutory powers, but denies the allegations in paragraph 21, and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca.
- 22. States that paragraph 22 consists of Plaintiff's characterizations of this action, to which no response is required, otherwise denies the allegations in paragraph 22, and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca.
- 23. Denies the allegations in paragraph 23 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme" or "Best Price Scheme," as alleged in paragraph

23, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 as to the other parties.

#### II. PARTIES

#### A. Plaintiff

- 24. Admits that Plaintiff State of Nevada purports to bring this action as alleged in paragraph 24, but denies any allegations or characteristics in paragraph 24, denies that Plaintiff has any basis in fact or law to maintain this action against AstraZeneca, and refers to the referenced statutes for their content, which speak for themselves.
- 25. Denies the allegations in paragraph 25 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25 as to the other parties and entities.
- 26. Admits that AZPLP sells and/or distributes products in the United States, including Nevada, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 as to the other parties and entities.

#### B. Defendants

#### 1. Amgen

27-28. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 27-28.

#### 2. AstraZeneca

29. Denies the allegations in paragraph 29, except admits that Zeneca Inc. is a Delaware corporation with its principal place of business located

at 1800 Concord Pike, Wilmington, Delaware, and further admits that Zeneca Inc. is an indirect subsidiary of AstraZeneca PLC, a public limited liability company organized under the laws of England and Wales.

- 30. Denies the allegations in paragraph 30.
- 31. Denies the allegations in paragraph 31, except admits that AZPLP is a Delaware corporation, with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware, and further admits that AZPLP is an indirect subsidiary of AstraZeneca PLC, a public limited liability company organized under the laws of England and Wales.
- 32. Denies the allegations in paragraph 32, except admits that Plaintiff purports to refer collectively to the entities listed as "AstraZeneca."
- 33. Denies the allegations in paragraph 33, except admits that AZPLP manufactures several drugs which may, under certain circumstances, be reimbursable under the Nevada Medicaid Program.

#### 3. The Aventis Group (Aventis Pharma, Hoechst and Behring)

34-39. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 34-39.

#### 4. The Boehringer Group (Boehringer, Ben Venue, Bedford)

40-44. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 40-44.

#### 5. Braun

45-47. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 45-47.

#### 6. The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)

48-51. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 48-51.

#### 7. Immunex

52-54. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 52-54.

### 8. The Johnson & Johnson Group (J&J, Centocor, Janssen, McNeil, Ortho)

55-60. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 55-60.

#### 9. Novartis

61-62. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 61-62.

#### 10. Pfizer, Inc.

63-64. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 63-64.

#### 11. The Schering-Plough Group (Schering Plough & Warrick)

65-68. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 65-68.

#### 12. The Sicor Group (Sicor and Gensia)

69-74. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 69-74.

#### 23. Watson

75-76. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 75-76.

#### III. PRESCRIPTION DRUG SPENDING

- 77. Denies the allegations in paragraph 77.
- 78-82. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 78-82, and refers to the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook Update*, dated November 2001, and the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraphs 78-82, for their content, which speak for themselves.
- 83. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83, and refers to the *Kaiser Family Foundation, Medicare And Prescription Drugs Fact Sheet*, dated April 2003, for its content, which speaks for itself.
- 84-86. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 84-86, and refers to the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook Update*, dated November 2001, and the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraphs 84-86, for their content, which speak for themselves.
- 87. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 87.
- 88. Denies the allegations in paragraph 88 to the extent that they are directed at AstraZeneca, specifically denies that AstraZeneca has committed any "fraud," and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 88 as to the other parties.

#### IV. THE PRESCRIPTION DRUG MARKET

- 89. Admits the allegation in paragraph 89 that specialized terminology exists in the pharmaceutical industry, but denies the remaining allegations in paragraph 89, and specifically denies the existence of or participation in "frauds and schemes" as alleged in paragraph 89.
  - 90-92. Admits the allegations in paragraphs 90-92.
- 93. Admits the allegation in paragraph 93 that a brand-name drug may or may not have a generic equivalent, depending upon a variety of factors, including whether the patent has expired and whether a generic manufacturer has produced a generic version, but denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 93.
- 94. Denies the allegations in paragraph 94, but admits that AZPLP distributes most of its products through one or more of several different types of entities, including, wholesalers, retailers, hospitals, and providers, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 94 as to other parties.
- 95. Denies knowledge or information sufficient to form a belief as to the truth of the allegations stated in paragraph 95, and refers to the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraph 95, for its content, which speaks for itself.
- 96. Denies the allegations in paragraph 96, but admits that Wholesale Acquisition Cost ("WAC") is generally the list price for sales by manufacturers to wholesalers.

- 97. Admits that some private and public drug reimbursement systems reimburse based upon AWP, but denies knowledge or information sufficient to form a belief as to the allegations stated in the first sentence of paragraph 97, and denies the remaining allegations in paragraph 97.
- 98. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 98, and refers to the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraph 98, for its content, which speaks for itself.
- 99-100. Denies the allegations in paragraphs 99-100 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 99-100 as to the other parties.
- 101-102. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 101-102.
- 103. Admits the allegations in the first sentence of paragraph 103, but denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 103.
- 104. Denies knowledge or information sufficient to form a belief as to the truth of the allegations stated in paragraph 104, and refers to the *Kaiser Family Foundation, Prescription Drug Trends: A Chartbook*, dated July 2000, referenced in paragraph 104, for its content, which speaks for itself.
- 105. Denies the allegations in paragraph 105 to the extent they are directed at AstraZeneca and otherwise denies knowledge or information sufficient

to form a belief as to the truth of the allegations in paragraph 105 as to the other parties.

106. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 106.

### V. GOVERNMENT REIMBURSEMENT SYSTEMS FOR PRESCRIPTION DRUGS

- 107-109. Admits the allegations in paragraphs 107-109.
- 110. Refers to the *CCH* Article, "Medicare Explained," referenced in paragraph 110, for its content, which speaks for itself, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 110.
- 111. Admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth in 42 C.F.R. § 405.517, which is referenced in paragraph 111, and refers to 42 C.F.R. § 405.517, for its content, which speaks for itself.
- 112. Denies the allegations in the first sentence of paragraph 112 insofar as it contains material in quotation marks, the source of which is not identified. AstraZeneca further denies the second sentence of paragraph 112 insofar as 42 C.F.R. § 405.517 contains no reference to a "ceiling" on reimbursement amounts.
- Denies knowledge or information sufficient to form a belief as to the truth of the allegation regarding the date of the amendment, and otherwise admits the allegations in paragraph 113.

- 114-115. Admits that the Medicare Program has publicly announced that it would use the AWP published in independently produced compendia as the basis for reimbursement, and refers to Program Memorandum AB-99-63, referenced in these paragraphs, for its content, which speaks for itself.
- 116. Admits that there are no regulations describing how AWPs are to be calculated, or regulatory process for approving them, denies the remaining allegations in paragraph 116 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 116 as to the other parties.
- 117-118. Admits the allegations in paragraphs 117-118, except denies that a 20% co-payment is always paid by a Medicare Part B beneficiary.
- 119-121. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 119-121, and refers to *Medicaid and Prescription Drugs: An Overview*, dated October 2000, referenced in paragraphs 119-121, for its content, which speaks for itself.
- 122. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 122, refers to *Kaiser Commission on Medicaid and the Uninsured, Medicaid Facts: Medicaid and Prescription Drugs*, dated October 2000, referenced in paragraph 122, for its content, which speaks for itself.
- 123. Refers to the statutes and regulations governing the Medicare and Medicaid Programs for their content, which speak for themselves.

- Refers to 42 C.F.R. § 440.120, and the statutes and regulations governing the Nevada Medicaid Program for their content, which speak for themselves.
- 125. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125.
- 126. Refers to the *Nevada Medicaid Services Manual* § 1204.2, for its content, which speaks for itself, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 126.

#### VI. AWP ALLEGATIONS

- 127. Denies the allegations in paragraph 127, but admits that AWPs play a role in various prescription drug reimbursement systems that operate in the United States.
- 128. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 128, except admits that prescription drugs are dispensed to patients by different types of medical providers including physicians, hospitals and pharmacies.
- 129. Admits that some private and public drug reimbursement systems reimburse physicians and pharmacies for certain prescription drugs based upon AWP, but otherwise denies the allegations in paragraph 129 to the extent they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 129 as to the other parties and entities.

- 130. Admits that several independently produced compendia periodically publish AWPs for various prescription drugs, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 130.
- 131-132. Denies the allegations in paragraphs 131-132 to the extent that they are directed at AstraZeneca, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 131-132 as to the other parties and entities, except admits that prior to January 2002, AstraZeneca reported suggested AWPs for certain pharmaceuticals to independently produced pricing compendia, and refers to the Foreward to the 1999 edition of the *Red Book*, the June 1996 *Dow Jones* news article, and the Dey Complaint referenced in paragraph 131, for their content, which speak for themselves, but denies any characterization of these documents.
- 133-134. Denies the allegations in paragraphs 133-134 to the extent they are directed at AstraZeneca, and refers to the April 2003 Office of the Inspector General ("OIG") Report, referenced in paragraphs 133-134, for its content, which speaks for itself, but denies any characterization of this document.
- 135. Denies the allegations in paragraph 135 to the extent they are directed at AstraZeneca, specifically denies the existence of, or participation in, the fraudulent or unlawful manipulation of AWPs, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 135 as to the other parties.

#### VII. THE PURPORTED AWP INFLATION SCHEME

136-138. Denies the allegations in paragraphs 136-138 to the extent they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme" as alleged in paragraphs 137-138, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 136-138 as to the other parties and entities.

139-143. Denies the allegations in paragraphs 139-143 to the extent they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "scheme" as alleged in paragraphs 140, 141 and 143, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 139-143 as to the other parties, except admits that prior to January 2002, AstraZeneca reported suggested AWPs for certain pharmaceuticals to independently produced pricing compendia.

144-147. Denies the allegations in paragraphs 144-147 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 144-147 as to the other parties.

148-163. Denies the allegations in paragraphs 148-163 to the extent that they are directed at AstraZeneca, specifically denies the existence of, or participation in, any "AWP Inflation Scheme," as alleged in paragraphs 148-163, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 148-163 as to the other parties.

164-165. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 164-165.

- 166-171. Denies the allegations in paragraphs 166-171 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 166-171 as to the other parties and entities.
- 172. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 172, and refers to *The Wall Street*Journal article dated March 30, 2003, referenced in paragraph 172, for its content, which speaks for itself.
- 173. Denies the allegations in paragraph 173, except admits that the federal government has been investigating drug marketing and pricing practices.
- 174-175. Denies the allegations in paragraphs 174-175 to the extent they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "scheme," as alleged in paragraph 174, denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 174-175 as to other parties and entities, and refers to the September 28, 2000 letter authored by Congressman Pete Stark, referenced in paragraphs 174-175, for its content, but denies any characterization of this document.
- 176. Denies the allegation in paragraph 176, except admits that the federal government has been investigating drug marketing and pricing practices.

#### E. EXAMPLES OF SPECIFIC CONDUCT

177-178. Denies the allegations in paragraphs 177-178 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 177-178

as to the other parties, except admits that Appendix A purports to be a list of drugs that Plaintiff alleges are subject to its asserted claims.

#### 1. Amgen

179-193. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 179-193.

#### 2. AstraZeneca

- denies the existence of, and participation in, any "scheme," as alleged in paragraph 194, and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca, except admits that Plaintiff alleges that the following drugs are at issue in this action: Accolate, Arimidex [misspelled Armidex in the Amended Complaint], Atacand, Atacand HCT, Casodex, Diprivan, Entocort, Nexium, Nolvadex, Prilosec, Pulmicort, Rhinocort, Seroquel, Toprol, Zestril, Zoladex, and Zomig.
- 196. Denies the allegations in paragraph 196, refers to the undated memorandum referenced in paragraph 196 for its content, which speaks for itself, but denies any characterization of this document.
- 197. Denies the allegations in paragraph 197, and specifically denies the existence of any "scheme," as alleged in paragraph 197.
- 198. Denies the allegations in paragraph 198, refers to the Guide to Coverage and Reimbursement referenced in paragraph 198 for its content, which speaks for itself, but denies any characterization of this document.

- 199-201. Denies the allegations in paragraphs 199-201, refers to the documents referenced in paragraphs 199-201 for their content, which speak for themselves, but denies any characterization of these documents.
  - 202. Denies the allegations in paragraph 202.
- 203-206. Denies the allegations in paragraphs 203-206, refers to the documents referenced in paragraphs 203-206 for their content, which speak for themselves, but denies any characterization of these documents.
  - 207. Denies the allegations in paragraph 207.
- 208-209. Denies the allegations in paragraphs 208-209, specifically denies the existence of, and participation in, any "scheme," as alleged in paragraph 209, and refers to the document referenced in paragraphs 208-209 for its content, which speaks for itself, but denies any characterization of this document.
- 210. Denies the allegation in paragraph 210, specifically denies the existence of, and participation in, any "scheme," as alleged in paragraph 210, and refers to the document referenced in paragraph 210 for its content, which speaks for itself, but denies any characterization of this document.
- 211. Denies the allegation in paragraph 211, and refers to the September 2001 GAO Report, referenced in paragraph 211, for its content, which speaks for itself, but denies any characterization of this document.
  - 212. Denies the allegations in paragraph 212.

- 213. Denies the allegations in paragraph 213, refers to the document dated July 17, 1995 referenced in paragraph 213 for its content, which speaks for itself, but denies any characterization of this document.
- 214. Denies the allegations in paragraph 214, refers to the indictment referenced in paragraph 214 for its content, but denies any characterization of this document.
  - 215. Admits the allegations in paragraph 215.
  - 216. Denies the allegations in paragraph 216.
- 217. Denies the allegations in paragraph 217, except admits that in June 2003, AZPLP entered into a settlement agreement with certain Federal and State government entities.
  - 218. Denies the allegations in paragraph 218.

#### 3. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

219-240. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 219-240.

#### 4. The Boehringer Group

241-255. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 241-255.

#### 5. B. Braun

256-272. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 256-272.

## 6. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

273-285. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 273-285.

#### 7. Immunex

286-301. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 286-301.

#### 8. The Johnson & Johnson Group (J&J, Centocor and Ortho)

302-316. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 302-316.

#### 9. Novartis

317-324. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 317-324.

#### 10. Pfizer

325-332. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 325-332.

#### 11. The Schering-Plough Group (Schering-Plough and Warrick)

333-350. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 333-350.

#### 12. The Sicor Group (Sicor, Gensia and Gensia Sicor)

351-368. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 351-368.

#### 13. Watson

369-382. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 369-382.

#### VIII. DEFENDANTS' PURPORTED "BEST PRICE" FRAUDS

383-389. Refers to 42 U.S.C. § 1396r-8 and the Rebate Agreement referenced in paragraphs 383-389, for their content, which speak for themselves, and further refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's "Best Price" claims for all AstraZeneca drugs except Zoladex.

390-391. Refers to the OIG Report, dated April 2003, cited in paragraphs 390-391, for its content, which speaks for itself, but denies any characterization of this document, and further refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's "Best Price" claims for all AstraZeneca drugs except Zoladex.

- 392. Denies the allegations in paragraph 392 to the extent they are directed at AstraZeneca, specifically denies the existence of, or participation in, any "artificial price inflation scheme," as alleged in paragraph 392, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 392 as to the other parties, and refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's "Best Price" claims for all AstraZeneca drugs except Zoladex.
- 393. Denies the allegations in paragraph 393 to the extent they are directed at AstraZeneca, refers 42 U.S.C. § 1396r-8, for its content, which speaks for itself, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 393 as to the other parties.
- 394. Denies the allegations in paragraph 394 to they extent they are directed at AstraZeneca, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 394 as to the other

parties, and refers to the OIG Report, dated March 2001, referenced in paragraph 394, for its content, which speaks for itself, but denies any characterization of this document.

395-397. Denies the allegations in paragraphs 395-397 to the extent they are directed at AstraZeneca, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 395-397 as to the other parties, and refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's "Best Price" claims for all AstraZeneca drugs except Zoladex.

- 398. Admits the allegation in paragraph 398.
- 399. Denies the allegations in paragraph 399.
- 400. Denies the allegations in paragraph 400, except admits that AstraZeneca entered into a settlement agreement with the Federal government and certain State governments.
- 401-403. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 401-403, and refers to the OIG Semiannual Report, dated October 2002-March 2003, referenced in paragraph 403, for its content, which speaks for itself.

#### IX. DEFENDANTS' PURPORTED CONCEALMENT OF THE TRUTH

- 404. Denies the allegations in paragraph 404 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 404 as to the other parties.
- 405. Denies the allegations in paragraph 405 to the extent they are directed at AstraZeneca, except admits that AZPLP sells its products in a

competitive market and consequently, that it takes steps to keep certain information relating to its pharmaceuticals confidential, refers to the CMS Health Care Industry Market Update dated January 10, 2003, referenced in paragraph 405, for its content, which speaks for itself, but denies any characterization of this document, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 405 as to the other parties.

- 406-409. Denies the allegations in paragraphs 406-409 to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 406-409 as to the other parties.
- 410. Denies the allegations in paragraph 410, and denies that there exists any basis in fact or law for the institution or maintenance of this action against AstraZeneca. AstraZeneca further denies that the Plaintiff did not receive inquiry or other notice of the issues associated with reliance on AWP as a pricing benchmark; on the contrary, such issues were well known before Plaintiff brought this suit. In addition, to the extent that paragraph 410 contains conclusions of law, AstraZeneca states that no response is required.
- 411-412. States that paragraphs 411-412 contain conclusions of law to which no response is required, otherwise denies the allegations in paragraphs 411-412 to the extent they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the other parties.

# X. ALLEGED DAMAGES SUSTAINED BY THE STATE OF NEVADA, PATIENTS AND THIRD-PARTY PAYORS

- 413. Denies the allegations in paragraph 413 to the extent that they are directed at AstraZeneca, specifically denies the existence of, and participation in, any "AWP Inflation Scheme," and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 413 as to the other parties.
- 414. Admits the allegations in paragraph 414, except denies that a 20% co-payment is always paid by a Medicare beneficiary.
- 415. Denies the allegations in paragraph 415 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations as to the other parties.
- 416. Denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 416.
- 417. Denies the allegations in paragraph 417 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations as to the other parties.
- 418. Admits that Medicare beneficiaries can obtain supplemental insurance to cover costs not paid by Medicare, but denies the remaining allegations in paragraph 418, and specifically denies the existence of, or participation in, any "AWP Inflation Scheme."
- 419-422. Denies the allegations in paragraphs 419-422, specifically denies the existence of, or participation in, any "AWP Inflation Scheme," and

otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 419-422 as to the other parties and entities.

#### XI. CLAIMS FOR RELIEF

#### **COUNT I**

# ALLEGED DECEPTIVE TRADE PRACTICES (Violations of NRS 598.0903, et seq.)

### CLAIM FOR DAMAGES ALLEGEDLY CAUSED TO NEVADA RESIDENTS

- 423. Answering for paragraph 423, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 422.
- 424. Denies that Plaintiff is entitled to maintain this action as alleged or to obtain any relief against AstraZeneca, and specifically denies the existence of, or participation in, any "AWP Inflation Scheme" as alleged in paragraph 424.
- 425. States that paragraph 425 (and its subparts) consists of conclusions of law to which no response is required, otherwise denies the allegations in paragraph 425 (and its subparts) to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 425 (and its subparts) as to the other parties.
- 426-428. Denies the allegations in paragraphs 426-428 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 426-428 as to the other parties.

- 429. States that paragraph 429 consists of a conclusion of law to which no response is required, otherwise denies the allegations in paragraph 429 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 429 as to the other parties. AstraZeneca further denies that Plaintiff has suffered any damages or injuries as alleged in paragraph 429.
- 429a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 429 of the Amended Complaint.

#### **COUNT II**

# ALLEGED DECEPTIVE TRADE PRACTICES DIRECTED AT ELDERLY NEVADA RESIDENTS (Violations of NRS 598.0973)

#### CLAIM FOR CIVIL PENALTIES AND INJUNCTIVE RELIEF

- 430. Answering for paragraph 430, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 429.
- 431. Denies that Plaintiff is entitled to maintain this action as alleged or to obtain any relief against AstraZeneca, and specifically denies the existence of, or participation in, any "AWP Inflation Scheme" as alleged in paragraph 431.
- 432. States that paragraph 432 (and its subparts) consists of conclusions of law to which no response is required, denies the allegations in paragraph 432 (and its subparts) to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a

belief as to the truth of the allegations in paragraph 432 (and its subparts) as to the other parties.

- 433. Denies the allegations in paragraph 433, specifically denies the existence of, or participation in, any "AWP Inflation Scheme," and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 433 as to the other parties.
- 434-435. Denies the allegations in paragraphs 434-435 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 434-435 as to the other parties.
- 436. States that paragraph 436 consists of a conclusion of law to which no response is required, otherwise denies the allegations in paragraph 436 to the extent they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 436 as to the other parties. AstraZeneca further denies that Plaintiff suffered damages or injuries as alleged in paragraph 436.
- 436a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 436 of the Amended Complaint.

#### **COUNT III**

# ALLEGED DECEPTIVE TRADE PRACTICES (Violations of NRS 598.0903, et seq.)

### CLAIM FOR CIVIL PENALTIES, INJUNCTIVE RELIEF, AND RESTITUTION FOR THE STATE OF NEVADA

- 437. Answering for paragraph 437, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 436.
- 438. Denies that Plaintiff is entitled to maintain this action as alleged or to obtain any relief against AstraZeneca, and specifically denies the existence of, or participation in, any "AWP Inflation Scheme" and "Best Price Scheme," as alleged in paragraph 438. Further, AstraZeneca refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's "Best Price" claims for all AstraZeneca drugs except Zoladex.
- 439. States that paragraph 439 (and its subparts) consists of conclusions of law to which no response is required, denies the allegations in paragraph 439 (and its subparts) to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 439 (and its subparts) as to the other parties. Further, AstraZeneca refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's "Best Price" claims for all AstraZeneca drugs except Zoladex.
- 440-442. Denies the allegations in paragraphs 440-442 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient

to form a belief as to the truth of the allegations in paragraphs 440-442 as to the other parties.

- 443. States that paragraph 443 consists of a conclusion of law to which no response is required, otherwise denies the allegations in paragraph 443 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 443 as to the other parties. AstraZeneca further denies that Plaintiff has suffered damages or injuries as alleged in paragraph 443.
- 443a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 443 of the Amended Complaint.

#### **COUNT IV**

# ALLEGED RACKETEERING (Violations NRS 207.400, et seq.)

### CLAIM FOR TREBLE DAMAGES TO STATE OF NEVADA AND CIVIL FORFEITURE

444-466. The Court dismissed Count IV in its Order dated June 10, 2004. As such, AstraZeneca does not respond to paragraphs 444-466. To the extent a response is required, AstraZeneca denies all allegations contained in Count IV of the Amended Complaint.